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Medicine Supply Notification: Rasagiline 1mg tablets

Tier 3 – high impact*

Date of issue: 16/11/2023

[Medicines Supply Tool – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

Summary

- Rasagiline 1mg tablets are in limited supply until mid-December 2023.
- Unlicensed supplies of rasagiline 1mg tablets may be sourced, lead times vary.
- Selegiline (*Eldepryl*®) 5mg and 10mg tablets remain available and can support increased demand.
- Safinamide (*Xadago*®) 50mg and 100mg tablets remain available and can support increased demand.

Actions Required

Primary and secondary care:

- Where practices in primary care identify patients on rasagiline, it is helpful to determine what supply they have left so arrangements can be made to put a management plan in place as soon as possible to minimise the risk of a break in treatment.
- Clinicians in secondary care should review patients admitted on rasagiline; where the hospital has no stock and the patient did not bring in their own supply, alternative management options should be considered, communicating any changes to primary care.
- Supplies of unlicensed rasagiline 1mg tablets can be sourced. Specialist teams should be consulted if this option is to be considered as it may not be viable for patients who have run out already or are low in supply due to the likely delay in obtaining these products. Contact should be made with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below).
- Patients on rasagiline who did not tolerate or respond to selegiline may be considered for a switch to safinamide (possibly off-label use in some cases) or an alternative agent based on specialist advice.
- Where possible, reserve any remaining stock for patients taking rasagiline as monotherapy or those who cannot tolerate or did not respond to selegiline.

Where clinicians are confident to safely switch patients to an alternative therapy, they should:

- consider prescribing selegiline (*Eldepryl*®) 5mg and 10mg tablets if not already trialled, where appropriate (see supporting information below for important safety considerations);
- counsel patients on the change to treatment and dosing, including reassurance that selegiline is a similar agent to rasagiline (see supporting information below), and advise them to report worsening of disease control, non-motor symptoms, mood, and/or side effects;
- signpost patients to Parkinson's UK helpline for further support/information, if required;
- inform the patient's specialist teams that treatment has been switched to selegiline; and
- liaise with the patient's specialist team for advice on management options if there is concern whether a washout period is required, or if the above option is not appropriate, or if patients experience a deterioration in disease control or troublesome side effects after switching.

Specialist teams should:

- ensure no new patients are initiated on rasagiline 1mg tablets if supplies are unavailable; and
- support primary care clinicians seeking advice on managing the switch to alternative treatment, including provision of an individualised management plan, where required

Supporting Information
Table 1: MAO-B inhibitors (refer to SmPC for full information)

Agent	Rasagiline	Selegiline	Safinamide
Type	Selective irreversible MAO-B inhibitor	Selective irreversible MAO-B inhibitor	Selective reversible MAO-B inhibitor
Indication	Treatment of idiopathic Parkinson's disease as monotherapy or as adjunct therapy (with levodopa) in patients with end of dose fluctuations.	Treatment of Parkinson's disease, or symptomatic parkinsonism. It may be used alone in early Parkinson's disease for symptomatic relief to delay the need for levodopa, or as an adjunct to levodopa.	Treatment of adult patients with idiopathic Parkinson's disease as add-on therapy to a stable dose of levodopa alone or in combination with other Parkinson's disease medicinal products in mid-to late-stage fluctuating patients
Dose	1mg once daily	10mg daily, either as a single dose in the morning or in two divided doses of 5mg, taken at breakfast and lunch.	50mg per day; may be increased to 100mg/day
Practice points	In practice, it is the preferred first line MAO-B inhibitor for most patients due to better tolerability profile than selegiline.	Different metabolic pathway to rasagiline and variation between respective SmPC's in what is classified as a caution and a contraindication, e.g., alcohol is a caution for rasagiline but contraindication for selegiline.	In practice, a last line oral treatment option and only to be initiated on the advice of a specialist, in line with local guidance.
Switching advice in SmPC*	At least 14 days must elapse between discontinuation of rasagiline and initiation of treatment with MAO inhibitors	No recommendation but caution that concomitant administration of selegiline and MAO inhibitors may cause central nervous and cardiovascular system disorders	At least 7 days must elapse between discontinuation of safinamide and initiation of treatment with MAO inhibitors

Switching MAO-B inhibitors*

Although the SmPC's for rasagiline and safinamide recommend a washout period to avoid serotonin syndrome and hypertensive crisis, in practice, neurologists may decide to switch patients without a washout to avoid worsening of fluctuations and prolonged off periods. It has been noted that the suspension of MAO-B inhibitors even for a few days can lead to a drastic deterioration in terms of worsening of motor and non-motor symptoms. The very limited published evidence on switching between agents suggests it can be carried out safely. An individualised approach as to the need for a washout period should be based on current disease control, comorbidities, and concomitant drugs, with advice sought from the specialist team if necessary

Please refer to the links below:

- SmPC: rasagiline 1mg tablets [Search Results - \(emc\) \(medicines.org.uk\)](#)
- SmPC: selegiline (*Eldepryl*®) 5mg and 10mg tablets [Eldepryl 5mg Tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)
- SmPC: safinamide (*Xadago*®) 50mg and 100mg tablets [Search Results - \(emc\) \(medicines.org.uk\)](#)
- BNF: Parkinson's disease [Parkinson's disease | Treatment summaries | BNF | NICE](#)
- CKS: Parkinson's disease [Parkinson's disease | Health topics A to Z | CKS | NICE](#)
- NICE guideline: Parkinson's disease in adults [Overview | Parkinson's disease in adults | Guidance | NICE](#)
- Parkinson's UK helpline [Helpline and Parkinson's advisers | Parkinson's UK \(parkinsons.org.uk\)](#)

Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed rasagiline 1mg tablets (please note there may be other companies that can also source supplies):

- Alium Medical
- Genetech Pharmaceuticals
- Mawdsley's unlicensed
- Target healthcare

- Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#),
 - [Prescribing unlicensed medicines - professional standards - GMC \(gmc-uk.org\)](#) General Medical Council (GMC)